4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0902]

# Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Prescription Drug Product Labeling; Medication Guide Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Prescription Drug Product Labeling; Medication Guide Requirements" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-7726, ila.mizrachi@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: On April 30, 2012, the Agency submitted a proposed collection of information entitled "Prescription Drug Product Labeling; Medication Guide Requirements" to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0393. The approval expires on January 31, 2016. A copy of the supporting statement for this information collection is available on the Internet at http://www.reginfo.gov/public/do/PRAMain.

Dated: May 8, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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